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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,110	08/31/2001	Andrew C Karaplis	SWA-XXX	5387

20988 7590 09/22/2004  
OGILVY RENAULT  
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CANADA

EXAMINER
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SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/806,110

Applicant(s)

KARAPLIS ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-10 AND 20-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-10 and 20-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Applicant's response filed 06/24/04 has been received.
2. New claims 20-28 have been entered.
3. Claims 7-10 and 20-28 are pending and under consideration.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-10 and 23-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons or record set forth in the previous office action of 11/23/03. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that newly presented claims 23-38 recite a functional equivalent of PEX and a PEX binding compound. As analyzed in the previous office action, the specification as filed does not provide complete structure for a sufficient number of the species of a broad genus. Additionally, the specification does not describe any guidance as to what would be other identifying characteristics for the compounds. Since all the compounds will have a function, recitation of a biological function cannot be considered an identifying characteristic.

### ***Response to Arguments***

Applicant's arguments filed 06/24/04 have been fully considered but they are not persuasive. Applicants argue:

The teachings of the present application provide a clear written description and enabling evidence of the modulation of PTH/PTHrP by PEX. More specifically, the

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However, applicants ignore the fact that the claims are drawn to any compound that- modulates PEX expression or activity that results in PTH and or PTHrP level modulation, any functional equivalent of PEX, however, the specification does not describe these broad genera of compounds and functional equivalents. Applicants arguments that the specification describes mechanism of PEX enzyme activity modulation (see page 5 first partial paragraph) does not address the written description requirement for the broad genera of compounds claimed. In the next paragraphs again applicants argue about their results about homology of PEX with NEP, again this does not provide written description for the claimed compounds. Description of interaction of Pex

6. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record set forth in the previous office action of 12/23/03. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is noted that the newly presented claims 20-28 are drawn to methods of treatment by modulating PTH and/or PTHrP by administering PEX or any functional equivalent of PEX or any modulator of PTH and /or PTHrP. The specification as filed does not provide sufficient guidance to practice any treatment method as discussed in the previous office action of 12/23/03.

### ***Response to Arguments***

Applicant's arguments filed 06/24/04 have been fully considered but they are not persuasive. Applicants argue that because they teach that PEX has homology with NEP, PEX modulates PTH/PTHrP, a skilled artisan would be able design PEX inhibitors/modulators or PEX binding substrate etc., the specification enables a method of treatment. However, treatment of a disease requires much more than experimentation in a cell line or test tube and an artisan would require specific

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guidance for designing and identifying compounds, their structure, mode of administration etc. for treating a disease and the specification as filed does not provide any guidance for treating a disease except for proposing that PEX or PEX binding compounds or modulators of PTH could be used for treating a disease. There is no clue as to what these compounds are, what is their structure and characteristics and without these specifics how could an artisan practice a method of treating a disease. Additionally, in view of the unpredictability of gene therapy discussed in the previous office action and lack of any specific guidance for gene therapy in the specification, an artisan could not practice the claimed methods.

Courts have stated, "It is true, as Genentech argues, that a specification need not disclose what is well known in the art. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." (See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966))

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7 and 8 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 7 and 8 are indefinite because they do not recite any method steps.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 7-10 and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/19246, June 27 1996) for reasons of record set forth in the previous office action of 12/23/03.

**11.** Claims 7-10 and 23-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Vickery et al (US 6,583,114 B2, June 24 2003) for reasons of record set forth in the previous office action of 12/23/03.

***Response to Arguments***

Applicant's arguments filed 06/24/04 have been fully considered but they are not persuasive. Applicants arguments that the claimed invention is different from the inventions of the cited arts because they do not teach modulation of PTH/PTHrP

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using PEX, however these arguments are not persuasive since the instantly claimed inventions are drawn to a method that comprises modulation of PTH/PTHrP as the end product of the method and since PTH hormone or its agonists would result in modulation of PTH/PTHrP, the claimed invention is anticipated by the teachings of Vickery et al or the WO 96/19246.

12. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

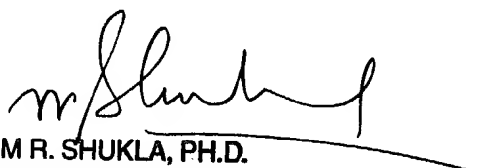
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735 . The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632



**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**